

PMH32**THE IMPACT OF DULOXETINE FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER ON THE QUALITY OF LIFE IN DEPRESSION SCALE**

Robinson RL, Obenchain RL, Croghan TW
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVE: Duloxetine hydrochloride, a potent and balanced dual reuptake inhibitor of serotonin and norepinephrine, previously has been shown to be safe and efficacious among patients with major depressive disorder, with efficacy measured by the Hamilton Depression Scale (HAM-D17). Our analyses show that treatment with duloxetine also has a favorable impact on quality of life.

METHODS: Adult patients (N = 353) from multiple centers throughout the United States were included in a double-blind, placebo- and active comparator-controlled clinical trial. Patients were randomized to duloxetine 40mg/day (administered 20mg/BID), duloxetine 80mg/day (administered 40mg/BID), paroxetine 20mg/day, or placebo, and followed for eight weeks. The protocol called for 3 repeated measures on the Quality of Life in Depression Scale (QLDS). The QLDS is a 34 item patient-reported, unidimensional, depression-specific measure, with lower scores indicating greater quality of life (increased capacity to satisfy one's own needs). To make area-under-the-curve comparisons, mixed-model estimation with random patient slopes and intercepts was used to singly impute missing values. Sensitivity analyses using Prediction plus Resampled Residual (PpRR) bootstrapping were used to verify that single imputation had not biased estimates associated with repeated measurements on either QLDS or HAM-D17.

RESULTS: Duloxetine 80mg/day consistently produced the lowest repeated QLDS scores. After adjusting for baseline differences, both duloxetine 80mg/day and paroxetine 20mg/day produce significantly lower ($p = 0.0001$) QLDS scores than placebo. But duloxetine 80mg/day patients reported significantly lower ($p = 0.002$ to 0.01) QLDS scores than paroxetine patients. Similar significance levels resulted when using HAM-D17 as the outcome.

CONCLUSIONS: In an 8-week randomized clinical trial, duloxetine 80mg/day improved patient-reported scores on QLDS in a way that is highly consistent with the corresponding improvements in HAM-D17 clinical measures. As many items from the QLDS and HAM-D17 are correlated, the overlap between quality of life and mood should be further investigated.

PMH33**QUALITY OF LIFE IN SCHIZOPHRENIA: THE RELATIONSHIP BETWEEN PARTICIPANT SELF-REPORT AND CLINICAL ASSESSMENT**

Russo P¹, Smith MW²

¹The MEDSTAT Group, Inc, Washington, DC, USA; ²VA Palo Alto Health Care System, Menlo Park, CA, USA

OBJECTIVE: To examine the relationship between self-reported and clinically assessed quality of life (QoL) among participants in the U.S. Schizophrenia Care and Assessment Program (SCAP).

METHODS: Data reflect measures obtained at the 12-month assessment period ($n = 908$). Clinical instruments were the Quality of Life Scale (QLS), Montgomery-Asberg Depression Rating Scale (MADRS), Positive and Negative Symptoms Scale (PANSS) and Abnormal Involuntary Movement Scale (AIMS). Self-report data were obtained from Life Satisfaction (LifeSat) scale and Depression scale, component scales of the SCAP Health Questionnaire. Cross-sectional regression analyses were conducted.

RESULTS: Correlation between the subjective and objective scale totals and component items were significant in most instances with magnitudes ranging from 0.2 to 0.6. Clinical rating of QLS was significantly and inversely impacted by PANSS ($p < 0.001$) and MADRS ($p < 0.001$). Unlike QLS, self-reported LifeSat was impacted by MADRS ($p < 0.001$) and not by symptoms (PANSS). The magnitude of effect of MADRS was 38% greater on LifeSat than on QLS. Two QLS sub-scales (common objects and activities [COA] and interpersonal relations [IPR]) exhibited a significant relationship with LifeSat ($p < 0.01$ and $p < 0.001$, respectively). In the presence of MADRS, however, significance of clinical symptoms and QLS subscales diminished and R-squared increased. Clinically assessed depression exhibited a significant relationship (0.38 ; $p < 0.001$) to self-reported depression.

CONCLUSIONS: The relationship of self-report to clinical assessment is of particular interest for persons with schizophrenia given the current climate of participatory treatment planning and outcome milestone achievement. These findings demonstrate several important points: 1) participant self-reports and clinical assessments exhibit significant interrelation for both QoL and depression; 2) clinical symptoms and side effects are not important drivers of self-reported QoL; 3) level of depression is an important factor in patients' own sense of life satisfaction; and 4) depression scores exhibit a mediating effect between psychiatric symptom presentation and valuation of quality of life.

PMH34**PSYCHOMETRIC EVALUATION OF THE MODIFIED STRAIN IN NURSING CARE ASSESSMENT SCALE**

Ciesla G¹, Frank L¹, Kleinman L¹, Brodaty H², Rupnow M³

¹MEDTAP International, Bethesda, MD, USA; ²University of New South Wales, Sydney, Australia; ³Janssen Pharmaceutica Products, L.P., Titusville, NJ, USA

OBJECTIVES: The objective of this study was to evaluate the psychometric properties (reliability and validity) of the Modified Strain in Nursing Care Assessment Scale (M-NCAS), a 32-item scale for assessing dementia-related behaviors and the extent of job burden caused by those behaviors.